K091674

JAN 15 2010

510(k) Summary

ArthroCare® Corporation
ArthroCare® Coblator IQ™ System

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	December 18, 2009

Device Description

Trade Name:	ArthroCare® Coblator IQ™ System
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (Class II, 21 CFR 878.4400, Product Code 79G - - EI)

Predicate Devices

ArthroCare Coblator ENT Surgery System	K030108 (February 3, 2003)
ArthroCare 8000S Coblator Surgery System	K053297 (December 6, 2005)
ArthroCare Irrigation Pump	K080482 (March 20, 2008)

Product Description

The ArthroCare Coblator IQ System is a bipolar, high frequency, electrosurgical generator called the Controller that is intended to be used with a family of disposable, bipolar, single use Wands.

Intended Uses

The ArthroCare Coblator IQ System is indicated for the following procedures:

- For resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in spinal and neurological procedures; and
- For ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:
  - Adenoidectomy
  - Cysts
  - Head, Neck, Oral, and Sinus Surgery
  - Mastoidectomy
  - Myringotomy with Effective Hemorrhage Control
  - Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
  - Nasopharyngeal/Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
  - Neck Mass
  - Papilloma Keloids
  - Submucosal Palatal Shrinkage
  - Submucosal Tissue Shrinkage
  - Tonsillectomy
  - Traditional Uvulopalatoplasty (RAUP)
  - Tumors
  - Tissue in the Uvula/Soft Palate for the Treatment of Snoring

Substantial Equivalence

In establishing substantial equivalence to the predicate device, ArthroCare compared the indications for use, dimensional specifications, and performance specifications of the subject device and the predicate device. Additionally, performance testing has been completed to demonstrate the substantial equivalence of the ArthroCare Coblator IQ System to the predicate devices. The performance testing and device comparison demonstrated that the subject device is substantially equivalent to the predicate device, and is safe and effective for its intended use.

Summary of Safety and Effectiveness

The ArthroCare Coblator IQ System, as described in this premarket notification 510(k), is substantially equivalent to the predicate device. The differences in performance specifications and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Arthrocare Corporation
% Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085

JAN 15 2010

Re: K091674
Trade/Device Name: ArthroCare® Coblator IQ™ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 18, 2009
Received: December 22, 2009

Dear Ms. Defiesta-ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name ArthroCare® Coblator IQ™ System

510(k) Number: K_____

Indications for Use:

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  - Neck Mass
  - Papilloma Keloids
  - Submucosal Palatal Shrinkage
  - Submucosal Tissue Shrinkage
  - Tonsillectomy
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  - Tumors
  - Tissue in the Uvula/Soft Palate for the Treatment of Snoring

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

FOR M. MELKERSON
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091674